

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today  
(1) was not written for publication in a law journal and  
(2) is not binding precedent of the Board.

Paper No. 149

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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HENRY T. KEUTMANN, PETER SCHOFIELD,  
HENRY RODRIQUEZ, BETTY EIPPER  
and RICHARD MAINS,  
Junior Party,<sup>1</sup>

v.

JAMES P. GILLIGAN and BARRY N. JONES,  
Junior Party,<sup>2</sup>

v.

KAZUHIRO OHSUYE, KATSUHIKO KITANO,  
SHOJI TANAKA, HISAYUKI MATSUO  
and KENSAKU MIZUNO,  
Senior Party.<sup>3</sup>

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<sup>1</sup>Application 07/096,447, filed September 15, 1987.  
Assigned to Johns Hopkins University, Baltimore, Maryland, a  
corporation of Maryland.

<sup>2</sup>Application 07/086,161, filed August 14, 1987. Assigned  
to Unigene Laboratories, Inc., Fairfield, New Jersey, a  
corporation of Delaware.

<sup>3</sup>Application 07/219,375, filed July 15, 1988. Accorded  
the benefit of Japan SN 62-177184, filed July 17, 1987; and  
Japan SN 62-306867, filed December 5, 1987. Assigned to

Interference No. 102,700

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Patent Interference No. 102,700

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FINAL HEARING: May 14, 1998

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Before CAROFF, METZ, and ELLIS, Administrative Patent Judges.  
CAROFF, Administrative Patent Judge.

RECONSIDERATION

Gilligan et al. (Gilligan) has filed a request for reconsideration (Paper No. 147) of our Final Decision of September 22, 1999 (Paper No. 146). Ohsuye et al. (Ohsuye) has filed an opposition (Paper No. 148) to Gilligan's request for reconsideration.

Pursuant to 37 CFR § 1.658(b), a decision on reconsideration is limited to a determination of whether any points were misapprehended or overlooked by a Board panel in rendering a final decision. We have carefully considered the arguments advanced in Gilligan's request for reconsideration,

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Suntory Limited, Osaka, Japan, a corporation of Japan.

Interference No. 102,700

but we are not convinced that we misapprehended or overlooked any points in rendering our Final Decision.

According to Gilligan, our decision was based on a misapprehension that Gilligan "admitted" that its generic product claims 71-74 were not enabled by the relevant specification. This is not correct. A careful perusal of our decision reveals that we never implied that junior party Gilligan "admitted" that its generic "PAM" product claims were nonenabled. What we did say was that the party Gilligan does not dispute the holding in the Decision on Motions (Paper No. 79) that its generic product claims 71-74 (relating to purified PAM protein) go beyond the scope of enablement provided in its specification. In this regard, see pages 3-4 and 7 of our Final Decision. In fact, this was made abundantly clear by Gilligan on several occasions. For instance, see Gilligan's Statement of Issues (Paper No. 130-1/2), and pages 1 and 33 of Gilligan's Brief (Paper No. 138).

In the Decision on Motions (page 5), it was specifically held that the generic product claims 71-74 are beyond the scope of enablement provided by Gilligan's involved and parent application. The holding of nonenablement was premised upon a

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consideration of appropriate factors relevant in determining whether undue experimentation would be involved in practicing the full scope of the claimed invention. These factors include, inter alia, the scope of the working examples, the breadth of the claims, the nature of the invention, the state of the prior art, and predictability or unpredictability of the art, as enumerated in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) and Ex parte Forman, 230 USPQ 546, 547 (BPAI 1986). Thus, the finding in the Decision on Motions that Gilligan's generic product claims are not enabled stands undisputed in this case. This undisputed finding, and not any admission on the part of Gilligan, was deemed to be a significant factor in our conclusions regarding the patentability of Gilligan's generic method claims 76-79, 81-84 and 86-92.

Gilligan also charges us with misapprehending the significance of statements made by party Gilligan during prosecution of its parent application 06/655,366 in an amendment filed on June 6, 1986 (OR 220-235). In relevant part, Gilligan made the following statements in that amendment:

The Office Action also draws the conclusion that the presence of amidated peptides in a particular tissue is synonymous with high levels of alpha-amidating enzyme. This is not true. For example, rat anterior pituitary tissue contains high alpha-amidating activity but no known substrates [Eipper et al., PNAS 80, 5144-5148 (1983)]. Rat posterior pituitary tissue contains amidated peptides (oxytocin and vasopressin) but has very little alpha-amidating activity [Eipper et al., Endo 116, 2497-2504 (1985)]. Therefore, until individual tissues are tested for alpha-amidating activity, the presence or potential levels of the enzyme can not be anticipated. In fact, Applicants had to screen large numbers of tumors prior to identifying a tumor series with high levels of amidating enzyme activity; many of them were found to be unreliable or useless as enzyme sources. [OR-231]

According to Gilligan, the foregoing statement relates to difficulties encountered in developing the invention prior to the filing date; and Gilligan insists that those difficulties dissipated once the purification technique described in Gilligan's specification was developed. However, as we see it, Gilligan's statements are tantamount to an admission that identifying sources of PAM enzyme was unpredictable at the time the Gilligan application was filed. Gilligan has adduced no evidence that the identification of particular sources for the enzyme became more predictable as a result of Gilligan's development of a purification technique for extracting the enzyme from an identified source. Rather, by Gilligan's own

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admission, there is a need to screen a large number of potential sources, by species and tissue type, in order to identify a suitable source of PAM enzyme. Moreover, according to Gilligan, identification is further complicated by the fact that detection of the presence of amidated peptides is not a reliable indicator of the presence of the enzyme being sought. It is not seen how the development of a particular purification technique by Gilligan reduces the uncertainties involved in identifying a suitable source for purification.

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Finally, we note that Gilligan's request for reconsideration (p. 5) includes a list of potential sources of PAM enzyme which were mentioned in Gilligan's involved application or in prior art publications. Gilligan's application does list a number of publications which purportedly report the presence of "alpha-amidating enzyme activity" or "amidated peptides" in a variety of sources. However, in view of the admitted lack of predictability in the art, the presence of amidated peptides or some other sign of alpha-amidating activity is not dispositive with regard to identification of a useful enzyme source.

For the foregoing reasons, we decline to modify our Final Decision in any respect.

RECONSIDERATION DENIED

MARC L. CAROFF	)	
Administrative Patent Judge	)	
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	)	
	)	BOARD OF PATENT
ANDREW H. METZ	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
JOAN ELLIS	)	

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Administrative Patent Judge )

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Attorneys for Keutmann et al.:

Banner, Birch, McKie & Beckett  
1001 G Street, N.W.  
Suite 1100  
Washington, D.C. 20001-4597

Attorneys for Gilligan et al.:

Ostrolenk, Faber, Gerb & Soffen  
1180 Avenue of the Americas  
New York, NY 10036-8403

Attorneys for Ohsuye et al.:

Donald L. Grudziecki  
Burns, Doane, Swecker & Mathis  
George Mason Building  
Washington & Prince Streets  
P.O. Box 1404  
Alexandria, VA 22313-1404